University of Southern California School of Pharmacy

Medication Therapy Intervention & Safety Documentation Program

User Manual (v 6.0, last updated 11/20/11)

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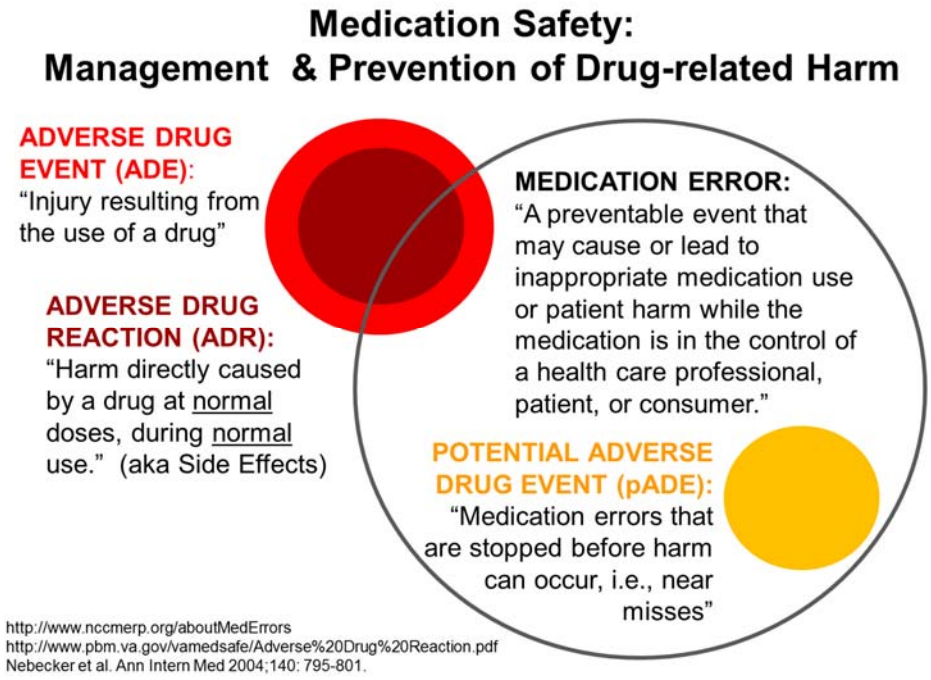
Background

In the course of ensuring optimal drug therapy through the spread of pharmacy services, many medication-related problems are identified and resolved. However, no national standard has been established for identifying, categorizing, and reporting medication safety interventions in the outpatient setting. This program adapts several multidisciplinary and/or national medication-related standards into a system for identifying, categorizing, rating severity of, and reporting the impact of pharmacy services on the quality and safety of medication use, including the detection of adverse drug events (ADEs) and potential adverse drug events (pADEs). For this manual, the term medication therapy intervention refers to any medication-related problem (MRP) identified requiring an action to resolve. If the medication-related problem is a safety issue, the problem either caused harm (ADE) or had the potential to cause harm (pADE). Definitions of ADEs and pADEs, as well as other medication safety terms, are provided in the following diagram and illustrated to clarify their relationships:


Medication Safety:
Management & Prevention of Drug-related Harm
ADVERSE DRUG EVENT (ADE):
"Injury resulting from the use of a drug"
ADVERSE DRUG REACTION (ADR):
"Harm directly caused by a drug at normal doses, during normal use." (aka Side Effects)
MEDICATION ERROR:
"A preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a health care professional, patient, or consumer."
POTENTIAL ADVERSE DRUG EVENT (pADE):
"Medication errors that are stopped before harm can occur, i.e., near misses"
http://www.nccmerp.org/aboutMedErrors
http://www.pbm.va.gov/vamedsafe/Adverse%20Drug%20Reaction.pdf
Nebecker et al. Ann Intern Med 2004;140: 795-801.

This manual describes how to complete the USC Medication Therapy Intervention & Safety Documentation Form and includes descriptions and examples of all categories. A database version of the form is available free of charge for FileMaker Pro users, but can easily be adapted for any commercial database or spreadsheet program.

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How to Use the Pharmacist Intervention and Medication Safety Documentation Form

The form provided is designed to document interventions for a single patient per page; 3 rows are provided to document up to 3 different interventions. If there are more than 3 interventions for a given patient, additional forms should be completed. An alternative form was previously developed that supported documentation for multiple patients per page, but through trial and error it was determined that limiting the form to one patient per page is better for supporting filing of the original forms and for quality control purposes.

PATIENT INFORMATION — Medication Therapy Intervention & Safety Documentation Form (version 7, 8/24/11)

Date	Site	MRN	DOB	Gender	Insurance	Ethnicity & Language	Point of Care	Initials	
/ /	☐ A ☐ B ☐ C ☐ D ☐ E		/ /	☐ M ☐ F	☐ None ☐ M-caid ☐ M-Care ☐ Other	☐ Caucasian ☐ Black ☐ Latino ☐ Asian ☐ Other ☐ English ☐ Non-English	☐ MTM / DSM ☐ Med review / pharmacy / dispensary	PharmD:___ Student:___	☐ Entered in computer database

Demographic information is collected on the top of the form including the intervention date and check boxes for the specific site (if there are multiple sites in the health system), medical record number (MRN), date of birth (DOB), gender, insurance status, ethnicity and whether English language is spoken.

Point of care refers to the type of pharmacy service being provided when the intervention was made. The purpose is to differentiate between those encounters that occur during a relatively more extensive medication therapy management [MTM] / disease state management [DSM] visit as opposed to brief encounter for medication review (e.g., pharmacist or student-conducted medication reconciliation) or counseling session in a pharmacy or dispensary. Initials by students or pharmacists will help with quality control reviews, and the check box Entered in computer database indicates that the information on the form has been transferred into a database or spreadsheet.

Intervention Documentation

As previously described, each form contains 3 rows to document up to 3 interventions (i.e., a single intervention per row). Enter the name(s) of the specific drug(s) involved in the first column and the indication(s) involved in the second column. For example:

S.T. is a 60 yo Hispanic female who presents for diabetes MTM. She has been experiencing what she describes as ~ 10 "really bad" hypoglycemic episodes since her last visit with her primary care provider. She claims that she has not changed her diet nor activity level. She checked her blood glucose levels during several of these episodes and the readings ranged from 60 to 70 mg/dL; she managed these episodes by consuming fruit juice or bread and rechecking her blood glucose every 15 minutes as directed. Upon completing your medication reconciliation, you find out that her dose of glyburide was recently increased from 10mg BID to 20mg BID.

Problem: S.T. was prescribed 40mg/day of glyburide, maximum dose is 20mg/day, 10mg/day is considered to be the maximum effective dose.

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
1.	Glyburide	DM2		A B C D E F G H I	i ii iii	101 102 103 104 105 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR			

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Next, enter the Intervention Codes that apply to the intervention. The Intervention Codes section of the form is outlined with a black bolded border.

Intervention Codes, Column I

The codes for the first column, MRP (Medication-Related Problem), are shown in the table at the bottom of the form. There are 28 different MRPs grouped by category; this grouping was derived from the Patient-Centered Primary Care Collaborative Medication Management resource guide (see http://www.pcpcc.net/files/medmanagepub.pdf):

- Appropriateness and Effectiveness: MRPs 1-4
- Safety (ADEs / pADEs): MRPs 5-18
- Nonadherence and Patient Variables: MRPs 18-22
- Miscellaneous: MRPs 23-28

Select the MRP code from the list in **I. Medication-Related Problem (MRP)**. It is highly recommended that you select a single MRP code for each intervention in order to support data aggregation. For multiple MRPs, itemize each in a single row. A complete description and examples of each MRP is provided in the Appendix.

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
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In the example, a total daily dose of glyburide at 40 mg/day is "excessive for treatment goals (dose, interval, or duration)" which is category number 5.

I. MEDICATION-RELATED PROBLEM (MRP)[1]

Appropriateness and Effectiveness
1. Untreated medical problem
2. Drug dosing not adequate for treatment goals (dose, interval, or duration)
3. Treatment not optimal based on current evidence / guidelines
4. Monitoring standards not being followed

Safety (pADE / ADE)
5. Drug dosing excessive for treatment goals (dose, interval, or duration)
6. Incomplete / improper directions
7. No indication for medication prescribed
8. Polypharmacy (Rx not needed) / duplication
9. Contraindication
10. Adverse drug reaction (ADR)
11. Allergy
12. Drug interaction
13. Lab/diagnostic test indicated, not ordered
14. Abnormal lab result not addressed
15. Pharmacy / dispensing error
16. Medication overuse or misuse
17. Dose discrepancy between patient use & prescribed therapy
18. Using expired medication(s)

Nonadherence and Patient Variables
19. Medication underuse / poor adherence
20. Dosage form is not reasonable for patient
21. Inadequate patient self-management of other non-drug variables
22. Patient dissatisfied or refuses treatment, no rational reason given

Miscellaneous
23. Drug not available in prescribed strength
24. Inadequate refills between scheduled visits
25. Nonformulary / not cost effective drug choice
26. Illegible prescription
27. No follow-up appointment with PCP
28. Other

II. ADE / pADE CLASSIFICATION[2]

Potential Adverse Drug Event (pADE)
A. No med error / event, but potential for ADE identified
B. Med error/event DID NOT reach patient
C. Med error/event reached patient, but no harm
D. Med error/event reached patient, monitoring or intervention required to confirm no harm

Adverse Drug Event (ADE)
E. Event occurred, resulting in temporary harm and requiring intervention
F. Event occurred, resulting in temporary harm and requiring hospitalization
G. Event occurred, resulted in permanent harm / disability
H. Event occurred, life-threatening
I. Event occurred, resulted in death

III. pADE SEVERITY RATING[3]
i. Potential for minimal (would require patient self-management) or no harm
ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)
iii. Potential for severe harm (permanent disability or death)

IV. INTERVENTION / RECOMM.
101. DC drug(s)
102. Substitute drug(s)
103. Add drug(s)
104. Change dose/dose interval
105. Change duration of tx / qty
106. Change PRN to schedule
107. Change schedule to PRN
108. Order lab / dx'tic test
109. Educate patient
110. Refer to other service
111. Clarify Rx
112. Substitute dosage form
113. Make appt w/ provider
114. Provide Rx compliance box
115. Other

Intervention Codes, Column II

Column II is to be completed ONLY if the MRP in **Column I** is #5 through #17, i.e., a safety problem that either resulted in some level of harm (ADE) or no harm (pADE, harm was avoided). If the MRP is #5 through #17, classify the ADE or pADE in **Column II** using categories A through I below under **II. ADE / pADE CLASSIFICATION**. This classification scheme is derived from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Medication Error Index (http://www.nccmerp.org/medErrorCatIndex.html). Wording has been slightly modified since NCCMERPs nomenclature is intended for categorizing ERRORS, whereas this program categorizes EVENTS. Letters A through D identify pADEs, i.e., medication errors or events that either did not reach the patient OR reached the patient but did not cause harm. Letters E through I identify ADEs that occurred resulting in varying levels of harm. Only one category can be selected in Column II.

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Safety (pADE / ADE)
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6. Incomplete / improper directions
7. No indication for medication prescribed
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9. Contraindication
10. Adverse drug reaction (ADR)
11. Allergy
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13. Lab/diagnostic test indicated, not ordered
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i. Potential for minimal (would require patient self-management) or no harm
ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)
iii. Potential for severe harm (permanent disability or death)

IV. INTERVENTION / RECOMM.
101. DC drug(s)
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103. Add drug(s)
104. Change dose/dose interval
105. Change duration of tx / qty
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107. Change schedule to PRN
108. Order lab / dx'tic test
109. Educate patient
110. Refer to other service
111. Clarify Rx
112. Substitute dosage form
113. Make appt w/ provider
114. Provide Rx compliance box
115. Other

Continuing with the example, since S.T.'s MRP is a safety (ADE / pADE) problem (#5-17) and S.T. experienced harm (hypoglycemia), the letter "E" should be circled in Column II, i.e., this is an ADE. The event that occurred resulting in temporary harm is hypoglycemia, and the intervention required was patient self-management followed by the changes made at this visit. If S.T. experienced a hypoglycemic event that required hospitalization, the appropriate Column II to select would be "F", "Error occurred, resulting in temporary harm and requiring hospitalization."

Intervention Codes, Column III

If category A through D is selected in **Column II**, then a pADE was identified and **Column III** must be completed. If any letter other than A through D was selected for **Column II**, then DO NOT complete **Column III**. The purpose of **Column III** is to classify the severity of the pADE. The premise for this categorization is that pADEs are broad-ranging in terms of what could have happened to the patient if the patient was harmed by the event, e.g., a patients who previously experienced an ACEi-cough who is re-prescribed the same ACEi vs. a patient with hyperkalemia and renal impairment prescribed spironolactone. Clearly the latter is a much higher-severity problem prevented. As a result, taxonomy was derived and simplified from Medicare Nursing Home Levels of Harm (http://www.medicare.gov/NHCompare/static/related/incdrawlevelofharm.asp?language=English&version=default) to provide 3 levels of potential harm severity, which are described in the table under "pADE Severity Rating". Only one severity category should be circled.

Our example involving S.T. does NOT apply for Column III since S.T. experienced harm / an ADE (hypoglycemia).

Using the brief examples cited above to illustrate the use of Column III:

- If a patient is prevented from receiving a prescription for an ACEi from which he or she previously experienced a confirmed ACEi-cough, then the MRP (Column I) would be **#10 (ADR),** the ADE / pADE Classification (Column II) would be **B (Med error / event DID NOT reach patient),** and the pADE Severity Rating (Column III) would be **i (Potential for minimal [would require patient self-management] or no harm).**

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- If a patient with hyperkalemia (K+ 5.6) and renal impairment who is already receiving ACEi therapy is prevented from receiving a prescription for spironolactone, then the MRP (Column I) would be **#9 (Contraindication),** the ADE / pADE Classification (Column II) would be **B (Med error / event DID NOT reach patient),** and the pADE Severity Rating (Column III) would be **ii (Potential for moderate harm [would require healthcare professional intervention or hospitalization to resolve]).**

I. MEDICATION-RELATED PROBLEM (MRP)[1]		II. ADE / pADE CLASSIFICATION[2]	III. pADE SEVERITY RATING[3]	IV. INTERVENTION / RECOMM.
Appropriateness and Effectiveness 1. Untreated medical problem 2. Drug dosing not adequate for treatment goals (dose, interval, or duration) 3. Treatment not optimal based on current evidence / guidelines 4. Monitoring standards not being followed **Safety (pADE / ADE)** 5. Drug dosing excessive for treatment goals (dose, interval, or duration) 6. Incomplete / improper directions 7. No indication for medication prescribed 8. Polypharmacy (Rx not needed) / duplication 9. Contraindication 10. Adverse drug reaction (ADR) 11. Allergy 12. Drug interaction 13. Lab/diagnostic test indicated, not ordered	14. Abnormal lab result not addressed 15. Pharmacy / dispensing error 16. Medication overuse or misuse 17. Dose discrepancy between patient use & prescribed therapy 18. Using expired medication(s) **Nonadherence and Patient Variables** 19. Medication underuse / poor adherence 20. Dosage form is not reasonable for patient 21. Inadequate patient self-management of lifestyle and other non-drug variables 22. Patient dissatisfied or refuses treatment, no rational reason given **Miscellaneous** 23. Drug not available in prescribed strength 24. Inadequate refills between scheduled visits 25. Nonformulary / not cost effective drug choice 26. Illegible prescription 27. No follow-up appointment with PCP 28. Other	**Potential Adverse Drug Event (pADE)** A. No med error / event, but potential for ADE identified B. Med error/event DID NOT reach patient C. Med error/event reached patient, but no harm D. Med error/event reached patient, monitoring or intervention required to confirm no harm **Adverse Drug Event (ADE)** E. Event occurred, resulting in temporary harm and requiring intervention F. Event occurred, resulting in temporary harm and requiring hospitalization G. Event occurred, resulted in permanent harm / disability H. Event occurred, life-threatening I. Event occurred, resulted in death	i. Potential for minimal (would require patient self-management) or no harm ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve) iii. Potential for severe harm (permanent disability or death)	101. DC drug(s) 102. Substitute drug(s) 103. Add drug(s) 104. Change dose/dose interval 105. Change duration of tx / qty 106. Change PRN to schedule 107. Change schedule to PRN 108. Order lab / dx'tic test 109. Educate patient 110. Refer to other service 111. Clarify Rx 112. Substitute dosage form 113. Make appt w/ provider 114. Provide Rx compliance box 115. Other

Intervention Codes, Column IV

This column must be completed for ALL interventions / MRPs. The codes for **Column IV** can be found in the last column of the table below under "**IV. Action/Intervention**."

More than one action/intervention code may be circled for each intervention / MRP.

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
1.	Glyburide	DM2	5	A B C D (E) F G H I	i ii iii	101 102 103 104 105 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR			

I. MEDICATION-RELATED PROBLEM (MRP)[1]		II. ADE / pADE CLASSIFICATION[2]	III. pADE SEVERITY RATING[3]	IV. INTERVENTION / RECOMM.
Appropriateness and Effectiveness 1. Untreated medical problem 2. Drug dosing not adequate for treatment goals (dose, interval, or duration) 3. Treatment not optimal based on current evidence / guidelines 4. Monitoring standards not being followed **Safety (pADE / ADE)** 5. Drug dosing excessive for treatment goals (dose, interval, or duration) 6. Incomplete / improper directions 7. No indication for medication prescribed 8. Polypharmacy (Rx not needed) / duplication 9. Contraindication 10. Adverse drug reaction (ADR) 11. Allergy 12. Drug interaction 13. Lab/diagnostic test indicated, not ordered	14. Abnormal lab result not addressed 15. Pharmacy / dispensing error 16. Medication overuse or misuse 17. Dose discrepancy between patient use & prescribed therapy 18. Using expired medication(s) **Nonadherence and Patient Variables** 19. Medication underuse / poor adherence 20. Dosage form is not reasonable for patient 21. Inadequate patient self-management of lifestyle and other non-drug variables 22. Patient dissatisfied or refuses treatment, no rational reason given **Miscellaneous** 23. Drug not available in prescribed strength 24. Inadequate refills between scheduled visits 25. Nonformulary / not cost effective drug choice 26. Illegible prescription 27. No follow-up appointment with PCP 28. Other	**Potential Adverse Drug Event (pADE)** A. No med error / event, but potential for ADE identified B. Med error/event DID NOT reach patient C. Med error/event reached patient, but no harm D. Med error/event reached patient, monitoring or intervention required to confirm no harm **Adverse Drug Event (ADE)** E. Event occurred, resulting in temporary harm and requiring intervention F. Event occurred, resulting in temporary harm and requiring hospitalization G. Event occurred, resulted in permanent harm / disability H. Event occurred, life-threatening I. Event occurred, resulted in death	i. Potential for minimal (would require patient self-management) or no harm ii. Potential for mo (would require healthcare professional intervention or hospitalization to resolve) iii. Potential for severe harm (permanent disability or death)	101. DC drug(s) 102. Substitute drug(s) 103. Add drug(s) 104. Change dose/dose interval 105. Change duration of tx / qty 106. Change PRN to schedule 107. Change schedule to PRN 108. Order lab / dx'tic test 109. Educate patient 110. Refer to other service 111. Clarify Rx 112. Substitute dosage form 113. Make appt w/ provider 114. Provide Rx compliance box 115. Other

In the current example, assume that the dosage for glyburide was reduced to 10mg BID. The appropriate selection would be "104: Change dose/dose interval."

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Description of event-

This last section must be completed if the intervention is an ADE (i.e., A, B, C, or D in **Column II**) or a Severity Rating ii or iii pADE (**Column IV**). This information is intended to help clarify the event and the likelihood that the event is associated with the drug. These details will allow the organization to easily compile a qualitative summary of important interventions to share with stakeholders. Separating the fields into brief descriptions of the Problem, Recommendation, and Outcome provides a simple format that, when summarized in a report, is easy to read and understand.

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
1.	Glyburide	DM2	5	A B C D E F G H I	i ii iii	101 102 103 104 106 107 108 109 110 111 112 113 114 115	☐ Yes ☐ Modified Yes ☐ No	☐ Yes ☐ No ☐ FTR	Glyburide increased from 10mg BID to 20mg BID by PCP, 10 episodes of hypoglycemia (FPG via SMBG 60-70)	Reduce glyburide to 10mg BID (A1C WNL before dose increase was made)	No hypoglycemia x 3 months, A1C 6.8%

Intervention Acceptance and Resolution of Medication-Related Problems (OPTIONAL FIELDS)

These two columns are optional. The first, **Intervention Acceptance,** should be completed if the action taken is a recommendation as opposed to an action that is implemented through a protocol or standing order. If the recommendation is accepted by the primary care provider, the "Yes" box should be checked. If the primary care provider agrees that the medication-related problem identified is a problem that needs to be acted upon, but changes the course of action recommended (e.g., chooses to add ezetimibe instead of increase the dose of statin for a patient who is not meeting LDL-C target), then the "Modified Yes" box should be checked. The "No" box is checked if the recosmmendation is not accepted.

The **Resolved?** column allows the user to track whether the problem identified was fully resolved. For interventions with a clinical or surrogate clinical outcome as a goal, "Resolved" is defined as achievement of the goal. Please note that "FTR" stands for Failed to Return.

INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

	Drug(s) involved)	Indication	Intervention Codes (see table below): I* MRP: (if #5-17 →)	II** For pADE/ADE: (if A-D →)	III** For pADE:	IV*** Intervention/ Recommend.:	Intervention Accepted? (optional) ****	Resolved? (optional)	Description of event- MUST complete for Severity ii or iii pADEs & all ADEs: Problem	Recommendation	Outcome
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Appendix: Definitions and Examples of Medication-Related Problems (MRPs)

APPROPRIATENESS AND EFFECTIVENESS

1. **Untreated medical problem**
   A medical problem that is not being addressed or treated.
   Examples:
   - *Post-MI patient with LDL-C above goal and no lipid-modifying therapy prescribed, no contraindications*
   - *No antiplatelet therapy for post-MI patient, no contraindication*
   - *Adult with Type 2 DM and albumin:creatinine ratio 76, no ACEi nor ARB and no contraindications*

2. **Drug dosing not adequate for treatment goals (dose, interval, or duration)**
   Dosing is insufficient to reach treatment goals based indication, recommended target dose, duration of therapy, etc.
   Examples:
   - *Adult with Type 2 DM and BP > 130/80 x last 3 visits, treated with lisinopril 2.5mg daily as monotherapy*
   - *Post-MI patient with LDL-C of 100 mg/dL receiving atorvastatin 40mg daily*
   - *Asthma patient with at least moderate persistent asthma receiving only Asmanex 1 inhalation QPM as controller therapy*

3. **Treatment not optimal based on current evidence / guidelines**
   Treatment deviates from clinical guidelines or current literature evidence without reasonable explanation such as contraindications or allergies to preferred therapies.
   Examples:
   - *Newly diagnosed obese adult Type 2 DM patient NOT receiving metformin*
   - *Moderate persistent asthma patient receiving Singulair as controller*
   - *Systolic dysfunction heart failure patient not receiving beta-blocker*

4. **Monitoring standards not being followed**
   Monitoring standards are not being applied to patient for a given treatment based on treatment guidelines and / or current evidence.
   Examples:
   - *Lipitor 10mg initiated over 1 year ago with no follow-up FLP ordered*
   - *Thyroid hormone replacement without f/u TSH, T4, T3 ordered*
   - *Spironolactone initiated, no follow-up BMP ordered*

SAFETY

5. **Drug dosing excessive for treatment goals (dose, interval, or duration)**
   Dose, interval or duration of a particular medication therapy exceeds guidelines or other evidence-based recommendations. Note that this is the opposite of #2.
   Examples:
   - *Toprol XL 100mg: 1 tab BID (Toprol XL should be taken once daily)*
   - *Glyburide 20mg: 1 tab BID (approved max = 20mg/day)*
   - *Ciprofloxacin 500mg: 1 tab BID x 3 months for UTI (inappropriate length of tx)*

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6. **Incomplete/improper directions**
   Prescription is incomplete or does not have proper instructions
   Examples:
   - *Ativan 0.5mg tablets: take as needed (missing dose, frequency, and indication)*
   - *Zofran ODT 4mg tablets: 1 tablet SL prn nausea/vomiting (should be ON the tongue)*

7. **No indication for medication prescribed**
   There is no medical condition for which this medication is indicated. This is different from #8 below in that there is NO indication.
   Examples:
   - *Patient receiving omeprazole 20mg QAM AC x 3 years with no GI condition diagnosed, patient has no recollection of why medication was given and cannot recall h/o GIB nor GERD sx's.*
   - *Patient has albuterol inhaler for PRN use, no diagnosis of pulmonary disease. Patient is nonsmoker with no recollection of h/o asthma, COPD, or related testing such as spirometry. Patient cannot recall why albuterol was prescribed.*

8. **Polypharmacy (Rx not needed) / Duplication**
   Although the patient has an indication for the medication, the medication is unnecessary for reaching treatment goals or duplicative of another medication.
   Examples:
   - *Patient is receiving an ACEi from your clinic through PAP but is also being prescribed lisinopril 10mg filled by CVS prescribed by a provider at another clinic (duplicative ACEi therapy)*
   - *Patient is using Advair 250/50 from your clinic through PAP but is also using Serevent inhaler from another provider (duplication in salmeterol therapy)*
   - *Patient with uncomplicated HTN is taking lisinopril 20mg daily, chlorthalidone 25mg daily, and sustained-release atenolol 25mg daily, BP 128/74. DC of atenolol results in BP 132/80. (atenolol unnecessary for reaching treatment goals)*

9. **Contraindication**
   Medication is contraindicated based on patient's age, medical history, laboratory data, laboratory tests, etc.
   Examples:
   - *Verapamil prescribed for patient with heart failure, EF 30%*
   - *Patient with hyperkalemia (K+ 5.6) and renal impairment who is already receiving ACEi therapy is prescribed spironolactone*
   - *32 yo female planning on becoming pregnant, prescribed ACEi*

10. **Adverse drug reaction (ADR)**
    An ADR is harm directly caused by a drug at normal doses during normal use. ADRs are side effects, but the term "side effects" tends to minimize the importance of the reaction and, therefore, ADR is the preferred terminology. These reactions may not necessarily be severe. Adverse drug reactions can be augmented pharmacologic effects, idiosyncratic effects, chronic effects, delayed effects, end-of-treatment effects, or failure of therapy. Please note that #11 below (Allergy) is a form of ADR, but is specifically mediated by the immune system.

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Examples:

- *Lower extremity edema from Norvasc 10mg daily for HTN*
- *Tylenol with Codeine #3 1-2 tabs q4-6h prn pain leading to severe drowsiness or constipation*
- *Cough from ACEi therapy*

11. Allergy

A specific form of ADR that is mediated by the immune system. The allergy can be to a new medication or to a medication that is re-prescribed to which the patient had a previous allergic reaction.

Examples:

- *Toddler is prescribed penicillin v potassium 250mg TID x 10 days for streptococcal infection for the first time, develops full-body rash, hives, and exhibits difficulty breathing*
- *Adult h/o NSAID-induced hives and SOB receives prescription for Celebrex*

12. Drug interaction

A drug-drug, drug-food, or drug-lab test interaction.

Examples:

- *Drug-drug: warfarin 5mg take as directed and ibuprofen 800mg 1 tab q8h prn pain (increased anticoagulation effect)*
- *Drug-food: Lipitor 10mg and >1 quart grapefruit juice daily (CYP p450 inhibition by grapefruit juice will increase serum Lipitor levels)*
- *Drug-lab test: Spironolactone resulting in falsely elevated digoxin level (via RIA)*

13. Lab/diagnostic test indicated, not ordered

A lab or diagnostic test is indicated for a patient based on diagnosis, comorbidities, etc. according to guidelines or current evidence, but has not been ordered.

Examples:

- *Patient is receiving clozapine without routine CBC with differential*
- *Adult patient with Type 2 DM x 7 years, no urine albumin-to-creatinine ratio test x past 2 years*

14. Abnormal lab result not addressed

Abnormal lab values returned for patient, action required but none taken.

Examples:

- *Recent CMP results include K+ 3.0, patient taking HCTZ 25mg daily, no action taken by PCP*
- *Recent AST/ALT is >3ULN, patient taking statin therapy and has received no follow-up instructions*

15. Pharmacy/dispensing error

Any error that occurs during the process of processing, filling, and dispensing medications to a patient.

Examples:

- *Patient was prescribed hydrochlorothiazide 25mg, but was dispensed hydroxyzine 25mg instead (wrong medication, dispensing error)*
- *Maria E. Hernandez is picking up her medications, but went home with Maria E. Fernandez's medications instead (wrong person, dispensing error)*
- *Label for simvastatin 20mg is placed onto Synthroid 200mcg bottle (wrong medication, dispensing error)*

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- *Prescriber writes for fentanyl 25mcg transdermal patches – 1 patch Q72H, but was typed and dispensed with "fentanyl 25mcg transdermal patches – 1 patch Q24H (typing error, dispensing error)*

16. Medication overuse or misuse

Patient is over/misusing a medication in a manner that he / she was not instructed or prescribed. This includes misuse of drug delivery and related devices. (Note: This is different from #2 and #5, where inadequate or excessive dosing is due to the prescriber. It is also different from #18, which is specifically underuse or poor adherence to medication.)

Examples:

- *ProAir HFA is prescribed as 1-2 puffs Q4-6H prn SOB/wheezing, but patient is taking 2 puffs Q2H while awake (overuse)*
- *Patient is swallowing Foradil capsules instead of inserting into Aerolizer and puncturing for inhalation*
- *Patient is using the adhesive overlay for Catapres-TTS instead of the medicated patch (misuse)*

17. Dose discrepancy between patient use and prescribed therapy

A situation where the current medication regimen listed in the medical record differs from how the patient is actually taking the medication, yet the patient has met treatment goals.

Example:

- *Medical record indicates that pt should be taking metformin 500mg BID, but pt is taking metformin 500mg daily with A1C consistently below 7%*

18. Using expired medication(s)

Patient is using medications that are expired or should no longer be used.

Example:

- *Patient continues to use insulin from vial beyond 30-day expiration*
- *Patient poorly-adherent with Foradil continues to use capsules beyond 4-month expiration*

NONADHERENCE AND PATIENT VARIABLES

19. Medication underuse/poor adherence

Patient is taking less than the prescribed dose / frequency / duration of medication

Examples:

- *Patient with persistent asthma who is not using QVAR inhaler*
- *Patient taking only 2 of 4 HTN medications which cannot be attributed to an ADE*

20. Dosage form is not reasonable for patient

Given the patient's circumstances, the dosage form is not appropriate / reasonable.

Examples:

- *Controlled-release medication prescribed to a patient who is NPO and has a G-Tube*
- *Burn victim patient with very little normal skin being prescribed transdermal patches*

21. Inadequate patient self-management of lifestyle and other non-drug variables

Patient not making necessary changes in lifestyle (e.g., diet, exercise, wt loss, smoking cessation) to help reach treatment goals

Examples:

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- *Diabetes patient continues to consume large amounts of foods with high sugar and carbohydrate content*
- *Heart failure patient consuming excessive amounts of salt and fluids, leading to frequent exacerbations*

22. Patient dissatisfied or refuses treatment, no rational reason given

Patient refuses treatment or states that he/she cannot and will not take a prescribed medication, no explanation or rational reason given.

Examples:

- *Refusal to start insulin therapy due to false beliefs about associated negative consequences (e.g., will result in blindness, dialysis) despite A1c of 12%*

MISCELLANEOUS

23. Drug not available in prescribed strength

Medication prescribed is not commercially available in strength requested.

Examples:

- *Mevacor 80mg (lovastatin does not come in 80mg)*
- *Toprol XL 150mg (Toprol XL does not come in 150mg)*

24. Inadequate refills between scheduled visits

Number of refills of medication are inadequate to last until next scheduled visit.

Examples:

- *Asthma patient receives Advair 250/50 with no refills, next appointment with PCP is 45 days later.*
- *Patient receives metformin 500mg i BID #60 with 2 refills, but next appointment with PCP is 4 months later.*

25. Nonformulary/not cost-effective drug choice

Provider prescribed a medication that is not on the formulary or a prior authorization is denied, and an alternative drug therapy appropriate for the patient is on the formulary.

26. Illegible prescription

Pharmacy personnel is unable to read the prescription.

27. No follow-up appointment with PCP

No follow-up appointment with a PCP has been made and the patient clearly needs follow-up care. This is a problem caused by the health system, not the patient, i.e., this problem is not to be used to identify patients who fail to keep follow-up appointments.

28. Other

Anything medication-related problem that is not described in the above categories.

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